

## REMARKS

Claims 15 and 24-28 are pending in this application.

As a preliminary matter, Applicants thank the Examiner for withdrawal of the prior claim rejections under 35 U.S.C. § 103, and the indication that claim 27 is allowable. Applicants request reconsideration of the new rejections under 35 U.S.C. § 103 in light of the amendments and remarks below.

### **I. Claim Rejections under 35 U.S.C. § 103**

Claims 15, 24, 26, and 28 are rejected under 35 U.S.C. § 103 as allegedly being obvious over U.S. Patent No. 5,902,814 (“Gordon”) in view of WO95/06470 (Scolnick) further in view of Stalker et al.

Gordon discloses the use of certain  $\alpha 7$  agonists in treating, *inter alia*, Alzheimer’s disease. The reference, however, does not teach or suggest the combination of such compounds with rosuvastatin, or any other statin.

To overcome this deficiency, the Office relies on Scolnick. A close reading reveals that Scolnick, indicates that the “HMG-CoA reductase inhibitors which are used in the method of this invention include” compounds of formula I, the open ring structures described on page 8, and compounds described on page 9. Notably, rosuvastatin does not fall within the boundaries of any of these formulas. Scolnick does not teach or suggest the use of rosuvastatin alone or in combination with other compounds. Nor does Scolnick disclose the combination of any statin with an  $\alpha 7$  agonist as claimed by Applicants.

To overcome this deficiency, the Office further combines Gordon and Scolnick with Stalker. Stalker is cited as indicating that rosuvastatin and simvastatin, ovastatin, fluvastatin, etc. have the same or similar function.

The motivation for such a combination comes from *in re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), which held it is *prima facie* obvious to combine two compositions, each of which is known to be useful for the same purpose, to form a combination for the same purpose. *In re Geiger*, 2 USPQ 1276 (Fed. Cir. 1986), however, indicates that there can be exceptions, for example where it is no more than obvious to try the various combinations, or where there are unexpected results.

Applicants specification indicates that statins, particularly rosuvastatin, reduce the formation of neurotoxic substance A $\beta$ .  $\alpha$ 7-nAChR agonists ameliorate cognitive deficits. Applicants teach the combination will result in enhanced efficacy over either agent alone, by potentially altering the pathophysiology of Alzheimer's disease and its symptoms. Such unexpected results are strong evidence of non-obviousness. The cited references are silent with respect to altering the pathophysiology of the disease by reducing the formation of the neurotoxic substance A $\beta$  as taught by Applicants. Only Applicants specification teaches such combinations will benefit from these enhanced effects. There is no teaching or suggestion in any of the cited references that the combination claimed by Applicants would have such enhanced effects. Accordingly, there is no motivation to combine the references and even if there were, there would be no expectation of such enhanced effects.

Applicants respectfully assert that the pending claims satisfy 35 U.S.C. § 103.

Claims 15, 25, 26, and 28 are rejected under 35 U.S.C. § 103, as being allegedly obvious over U.S. Application No. US2003/0018042 ("Eifion") in view of Jick and Stalker. Peters allegedly discloses (2'R)-5'-(3-furanyl)spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine] and its use in treating Alzheimer's disease. For reasons similar to those summarized above, the Office concludes that it would be *prima facie* obvious to combine (2'R)-5'-(3-furanyl)spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine] with

rosuvastatin to treat Alzheimer's disease. As discussed above, the cited references are silent with respect to altering the pathophysiology of the disease by reducing the formation of the neurotoxic substance A $\beta$  as taught by Applicants. Only Applicants specification teaches such combinations will benefit from these enhanced effects. There is no teaching or suggestion in any of the cited references that the combination claimed by Applicants would have such enhanced effects. Accordingly, there is no motivation to combine the references and even if there were, there would be no expectation of such enhanced effects. Applicants respectfully request that the claim rejections be withdrawn.

Applicants respectfully request reconsideration and allowance of all pending claims is respectfully requested in light of the comments herein.

The Commissioner is hereby authorized to debit any fee due or credit any overpayment to deposit account 26-0166.

Respectfully submitted,

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